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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,933	03/08/2006	Roland Callens	05129-00120-US	8950

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EXAMINER

PUTTLITZ, KARL J

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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05/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,933	Applicant(s) CALLENS ET AL.	
	Examiner KARL J. PUTTLITZ	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24 and 26-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 26-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The rejection under section 112, second paragraph is withdrawn in view of the amendments to the rejected claims.

The rejection under section 103 is maintained and repeated below. Applicant's remarks in connection with this ground of rejection are also addressed:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22- 24 and 26-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,097,490 to Reinhold (Reinhold).

The rejected claims cover, inter alia, a process for the manufacture of an enantiopure compound comprising at least one functional group capable of reacting with an activated carboxyl group, starting from a mixture of enantiomers of the said compound, in which process (a) a reaction medium comprising the mixture of enantiomers and a reagent based on an enantiopure amino acid, in which reagent at least one amino group of the amino acid is protected by a protective group and in which reagent at least one carboxyl group of the amino acid is activated, is subjected to conditions appropriate for bringing about the reaction of the functional group capable of

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reacting with the activated carboxyl group with the activated carboxyl group, so as to form a carbonyl bond; (b) the mixture of diastereomers obtained is subjected to a separation operation, so as to obtain at least one fraction composed essentially of a diastereomer; (c) at least a portion of the said fraction is subjected to a stage of cleavage of the carbonyl bond under conditions under which the protective group is essentially stable; and (d) the enantiopure compound and an enantiopure derivative of the amino acid in which at least one amino group is protected by the protective group are recovered.

The regard to the Above embodiments, Reinhold teaches a process for resolving mixtures of enantiomers of 1-t-butylamino-2,3-dihydroxypropane which comprises treating a solution of said mixture in a suitable solvent with an agent selected from S-pyroglutamic acid, R-pyroglutamic acid, L-(+)-tartaric acid and D-(-)-tartaric acid, separating, from the solution, solid diastereoisomer which forms and recovering from said diastereoisomer a single enantiomer of 1-t-butylamino-2,3-dihydroxypropane. See column 1, lines 55+.

Reinhold also teaches that the single enantiomer of 1-t-butylamino-2,3-dihydroxypropane is recovered from the separated diastereoisomer by conventional techniques. For example, the S-pyroglutamic acid.S-t-butylamino-2,3-dihydroxypropane diastereoisomer can be treated with a suitable base whereby the S-1-t-butylamino-2,3-dihydroxypropane is freed from the S-pyroglutamic acid. The S-1-t-butylamino-2,3-dihydroxypropane can then be recovered by extraction with a suitable solvent and the solvent stripped to yield the desired S-1-t-butylamino-2,3-dihydroxypropane. The

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neutralized S-pyroglutamic acid can be conventionally recovered from the remaining solution for re-use as a resolving agent. Another procedure for recovering the amine enantiomer from the separated diastereoisomer is to run a solution of the diastereoisomer through a suitable ion exchange resin column and then elute the free 1-t-butylamino-2,3-dihydroxypropane enantiomer. See description bridging columns 2 and 3.

The difference between the process set forth in the rejected claims and the process disclosed by Reinhold is that Reinhold fails to explicitly teach some of the specific amino protecting groups recited in the claims. However, it would have been obvious to substitute the S-pyroglutamic acid, R-pyroglutamic acid, L-(+)-tartaric acid and D-(-)-tartaric acid of the reference with the protected amino counterparts in order to obtain the predictable result of an enantiopure compound.

Applicant argues that the process according to the present invention leads to the formation of a carbonyl bond between the compound and the enantiopure amino acid reagent. However, the claim only requires the compound be capable of reacting with an activated carbonyl group. The compounds disclosed in Reinhold are capable of reacting with an activated carbonyl group, and thus, render the claim prima facie obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at telephone number (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karl J. Puttlitz/

Primary Examiner, Art Unit 1621